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10/524,228

02/09/2005

Alan John Johnstone

205139 (8830-308)

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7590 05/23/2008
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EXAMINER

NATNITHADHA, NAVIN

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

05/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---|---|--|
| Office Action Summary | Application No. 10/524,228 | Applicant(s) JOHNSTONE, ALAN JOHN | |
| | Examiner NAVIN NATNITHITHADHA | Art Unit 3735 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05092005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The status of the claims is as follows:

Claims 1, 9, and 11 are currently amended;

Claim 2 is as originally filed;

Claims 3-8 were previously presented; and

Claims 10 and 12-23 have been cancelled.
2. The 35 U.S.C. 112, second paragraph, rejections to claims 20 and 21 are

WITHDRAWN in view of their cancellation in the Amendment, filed 04 February 2008.

Response to Arguments

3. Applicant's arguments, see Remarks, pp. 4-5, filed 04 February 2008, with respect to the objection of the Information Disclosure Statement (IDS), filed 09 May 2005, as not compliant with 37 CFR 1.98(a)(3) have been fully considered, and are persuasive. The objection of the IDS has been withdrawn.
4. Applicant's arguments, see Remarks, p. 5, filed 04 February 2008, with respect to the objection of the Applicant's priority claim have been fully considered, and are persuasive. The objection of the priority claim has been withdrawn.
5. Applicant's arguments, see Remarks, pp. 5-7, filed 04 February 2008, with respect to the rejection of claims 1-23 under 35 U.S.C. 102(e) as being anticipated by

Khuri et al, U.S. Patent No. 6,567,679 B1 ("Khuri"), have been fully considered, but are moot in view of the new ground(s) of rejection.

Claim Objections

6. Claim 7 is objected to because of the following informalities: "communicating with, the fracture site" appears to be typographical error and should be amended to "communicating with the fracture site". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "the muscle" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 8, 9, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Dunn et al, U.S. Patent No. 5,766,432 A ("Dunn").

Claims 1-3, 8, 9, and 11: Dunn teaches the following:

a method of diagnosing a pathological condition of a patient's body tissue, e.g. muscles, bone, (see col. 1, ll. 29-30, col. 3, ll. 11-26), the method comprising: determining the presence or severity of ischaemia, e.g. shock, in the tissue by inserting a pH sensor into the tissue (see col. 6, ll. 13-23), directly measuring intracompartamental pH in the tissue (see col. 6, ll. 13-23), and using the intracompartamental pH measurement to diagnose the pathological condition, e.g. compartment syndrome (see col. 3, ll. 11-26), wherein a second sensor is used to measure the intracompartamental pressure in the tissue (see col. 6, ll. 13-23), wherein the reading from the sensor is compared with a calibrated scale to determine the extent of tissue damage (see col. 6, ll. 13-23).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn in view of Khuri.

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Claims 4-7: Dunn does not explicitly teach the following: the sensor is mounted on a catheter; the catheter is inserted into the muscle through a cannula, which is inserted into skeletal muscle in an orientation that is generally parallel to the muscle fibres or is inserted into the muscle adjacent to, but not communicating with the fracture site.

However, Khuri states (see col. 2, ll. 5-18):

There are several methods of delivery of a pH electrode, used in pH-guided myocardial management, to a site of interest. The electrode can be delivered manually by the user. The electrode can also be delivered by a catheter through a percutaneous incision. The electrode can also be delivered by an endoscope, a colonoscope or a laparoscope to a site of interest. Thus, in a preferred embodiment of the invention, the method can be applied to other tissue measurements such as brain tissue, kidney tissue, musculo-cutaneous flaps or the small or large intestines. In another embodiment, the pH of transplanted organs, such as liver or kidney, can be measured to assist in the diagnosis and/or treatment of rejection since acidosis is an early sign of rejection.

Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Dunn to incorporate the pH electrode 54 into a catheter in order to effectively deliver the electrode to a particular tissue of interest.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The other patents cited in the PTO-892 teach subject matter related to the Applicant's claims. The Examiner suggests reviewing these patents before responding to the present Office Action.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is (571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/N. N./
Patent Examiner, Art Unit 3735
05/19/2008